



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------------------|
| 09/581,890 | 08/28/2000 | Oliver Brustle | V0S-012 | 7106 |
| 7590 | 10/03/2003 | | | |
| Shann Kerner Hale & Dorr 60 State Street Boston, MA 02109 | | | | EXAMINER FALK, ANNE MARIE |
| | | | | ART UNIT 1632 PAPER NUMBER |

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|------------------------|-----------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/581,890 | BRUSTLE, OLIVER |
| | Examiner | Art Unit |
| | Anne-Marie Falk, Ph.D. | 1632 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires _____ months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on 25 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

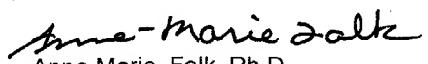
Claim(s) rejected: 2-15 and 46-51.

Claim(s) withdrawn from consideration: _____.

8. The proposed drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0803.

10. Other: _____


 Anne-Marie Falk, Ph.D.
 Primary Examiner
 Art Unit: 1632

Art Unit: 1632

Continuation Sheet (PTO-303)

Continuation of 2. NOTE:

The proposed amendment raises new issues that would require further consideration. Claims 2, 3, 6, 8-13, 15, 46-48, 50, 52-62, 74, and 75 recite the new limitation “or combinations thereof.” This new limitation would require further consideration.

Continuation of 5. does NOT place the application in condition for allowance because:

Although the Declaration of Dr. Bruestle remains unsigned, the Declaration has been fully considered.

Applicant argues that even a small number of undifferentiated or aberrantly differentiated ES cells suffice to cause tumors or foreign tissues in the graft (paragraph 11 of the Declaration). However, the claims cover cell compositions that comprise up to 15% primitive embryonic cells. As undifferentiated ES cells qualify as “primitive embryonic cells” the claim language allows for up to 15% undifferentiated ES cells remaining in the cell composition. As the claim also recites “wherein the cell composition is non-tumorigenic,” given Applicant’s arguments, the claim language is contradictory.

The Examiner accepts Applicant’s arguments that the cell compositions of Okabe et al. (1996) are tumorigenic. However, for the reasons indicated above, clarifying claim language is needed to overcome the rejection.

The standing grounds of rejection are maintained for reasons of record.